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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,765	01/14/2004	Per Egnelov	030481-0212	1510

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/756,765	Applicant(s) EGNELOV ET AL.	
	Examiner PATRICIA C. MALLARI	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-16 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9,11,15 and 16 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10,14 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 10, 14, 20-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "wherein the fluid communication pathway is formed between the insertion tube and the elongated member" and further recites "wherein the passage and the fluid communication pathway are adapted to permit the elongated member to be threaded in a substantially straight path there through". Each of claims 10, 14, and 20-22 contains similar language. The

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specification fails to describe an indicator system wherein the fluid communication pathway is formed between the insertion tube and the elongated member and wherein the fluid communication pathway is adapted to permit the elongated member to be threaded in a substantially straight path there through". Figure 1 of the instant application shows the indicator system, wherein the fluid communication pathway 6 can be considered to be merely the space within the tube 10, such that the pathway is configured to allow the elongated member to be threaded there through. In such a case, the pathway then is *not* formed between the insertion tube and the elongated member, and is therefore only formed between the walls of the insertion tube. It is further noted that the specification does describe figure as having a guide rod 5 inserted in the pathway 6 (see paragraph 28 of the instant specification). In the alternative instance in which the fluid communication pathway 6 is considered to be formed by the space between the elongated member 5 and the insertion tube 10, that space 6 is not configured to allow the elongated member to be threaded there through. It is noted that the instant specification *does not* describe the pathway as being formed between the insertion tube and elongated member.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 10, 14, 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “wherein the fluid communication pathway is formed between the insertion tube and the elongated member” and further recites “wherein the passage and the fluid communication pathway are adapted to permit the elongated member to be threaded in a substantially straight path there through”. Each of claims 10, 14, and 20-22 contains similar language. It is unclear how the fluid communication pathway can both be formed by the elongated member and permit the elongated member to be threaded there through, as claimed. See the rejection under 35 U.S.C. 112, 1st paragraph, set forth above, for details. If the pathway is said to be defined or formed between the insertion tube and the elongated member, the pathway cannot also be said to allow the elongated member to be threaded there through, since some portion of the elongated must define the pathway itself, and the pathway cannot receive a portion of itself within itself. Since the configuration as currently recited is impossible, and, as discussed, above, the instant specification discloses the guide rod or elongated member as being inserted within the pathway 6 (see paragraph 28 of the instant specification), the examiner is interpreting the recited language in accordance with the instant specification such that the limitation “wherein the fluid communication pathway is formed between the insertion tube and the elongated member” is ignored. This interpretation is made for the purpose of this examination only and to expedite prosecution. In any case, the applicants must address the current rejections under 35 U.S.C. 112, 1st and 2nd paragraphs.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 14, and 20-27 are rejected under 35 U.S.C. 102(b) as being unpatentable over US Patent No. 4,894,052 to Crawford. Crawford discloses an indicator system comprising a body having a passage passing through the body, a duct 20, 20a extending in the body, and a hemostatically sealed blood accommodating chamber 26 (see entire document, especially fig. 4; col. 6, lines 3-51 of Crawford). An insertion tube 11, 11a comprises a distal end adapted to be positioned inside a blood vessel, fluid communication pathway between an uncovered liquid inlet opening 21a near a distal end of the insertion tube and the duct 20, and an opening 12a at the extreme end of the distal end portion (see entire document, especially figs. 2 and 4; col. 5, lines 33-35; col. 6, lines 3-51 of Crawford). The inlet opening 21a is formed on an outer surface of the insertion tube 11, 11a (see entire document, especially figs. 2 and 4 of Crawford). A window 14 comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (see entire document, especially figs. 2 and 4; col. 4, lines 45-50; col. 5, lines 15-23 of Crawford). An elongated member 24 is adapted to be threaded in a substantially straight path through the passage and fluid communication pathway between a distal end of the insertion tube and a proximal end of the body, and an outer dimension of the elongated member and an inner

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dimension of the insertion tube are substantially equal to each other and are configured such that flow of blood between the outer and inner dimensions is prevented when the elongated member is inserted into the insertion tube (see entire document, especially fig. 4; col. 6, line 52-col. 7, line 17 of Crawford). The system of Crawford is capable of visually indicating a pressure of blood inside a blood vessel in that the flow of blood into the catheter is an indicator of blood pressure in the vessel.

Regarding claim 3, the duct opens into the chamber 26 via an aperture having a spill over edge, the edge being formed by the wall of the syringe expanding from a smaller to a larger diameter. The device is capable of being positioned such that the aperture is located at a level above a bottom of the chamber such that return flow of the blood back to the chamber is prevented (see entire document, especially fig. 4 of Crawford).

Regarding claim 4, the chamber 26 is located in the body and further comprises the insertion tube 11, 11a extending distally of the body (see entire document, especially fig. 4 of Crawford).

Regarding claim 5, the inlet opening 21a is located on a side of the insertion tube (see entire document, especially fig. 4 of Crawford).

Regarding claim 6, the device is capable of being positioned such that the duct extends vertically to an aperture opening into the chamber (see entire document, especially fig. 4 of Crawford).

Regarding claim 7, the duct extends horizontally above at least a portion of the chamber to an aperture opening into the chamber (see entire document, especially fig. 4 of Crawford).

Regarding claim 8, the duct 20, 20a exhibits a varying cross-section over its length (see entire document, especially fig. 4 of Crawford).

Regarding claims 10 and 14, the elongated member projects distally past the extreme end of the distal end portion of the insertion tube (see entire document, especially fig. 4; col. 6, line 52-col. 7, line 17 of Crawford). With further regard to claim 10, the body may instead be considered to have a duct 17, 17a extending in the body and a hemostatically sealed blood accommodating chamber 20, 20a, wherein the insertion tube comprises a fluid communication pathway between an uncovered liquid inlet opening 12a near a distal end of the insertion tube and the duct (see entire document, especially figs. 2 and 4; col. 6, lines 64-69 of Crawford).

Regarding claim 20, Crawford further discloses providing the indicator system as described above, positioning the distal end portion inside the blood vessel, and indicating the pressure (see entire document, especially col. 5, lines 2-23; col. 6, lines 3-30 of Crawford), wherein the appearance of blood in the chamber indicates blood pressure in the blood vessel. With further regard to the indicator system, the passage and fluid communication pathway are adapted to permit the elongated member 24 to be threaded in a substantially straight path there through between a proximal end of the body and a distal end of the insertion tube to plug, at least in part, the opening at the

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extreme end of the distal end portion (see entire document, especially fig. 4; col. 6, lines 3-30; col. 6, line 52-col. 7, line 17 of Crawford).

Regarding claim 21, the elongated member dilator, wherein the term dilator appears merely to indicate a use of the elongated member. A dilator is something that makes something else wider or larger, and the elongated member of Crawford is certainly capable of such a use.

Regarding claims 22 and 23, the elongated member is a guide rod or guide wire (see entire document, especially col. 5, lines 50-55 of Crawford).

Regarding claim 24, the indicator system is configured such that blood may flow from a region outside the insertion tube, through the inlet opening 21a and into an interior of the insertion tube 11, 11a (see entire document, especially figs. 2, 4 of Crawford). It is noted that the claim fails to recite that the recited blood flow occurs during a particular use of the system.

Regarding claim 25, when the opening 12a at the extreme end of the distal portion of the insertion tube is not blocked, the system is configured such that blood may flow from a region outside of the insertion tube, through the opening at the extreme end 12a and into an interior of the insertion tube 11, 11a (see entire document, especially figs. 2, 4 of Crawford).

Regarding claim 26, the elongated member is of a one-piece, solid construction (see entire document, especially fig. 4; col. 5, lines 46-col. 6, line 30 of Crawford), wherein figure 4 shows the guide wire 24 as being one piece.

Regarding claim 27, the outer surface of the insertion tube that forms the inlet opening is the entire outer surface of the tube 11, 11a. A portion of that surface is exposed to the blood vessel when the distal end portion of the insertion tube is positioned inside the blood vessel (see entire document, especially figs. 2 and 4 of Crawford).

Response to Arguments

Applicants' arguments filed 5/28/08 have been fully considered but they are not persuasive.

The applicants argue that Crawford does not disclose an insertion tube with both an inlet opening formed on an outer surface of the tube and an opening at an extreme end of the distal end portion. However, as stated in the previous Office action and above, the insertion tube 11, 11a does in fact include both an inlet opening 21a formed on an outer surface of the tube and an opening 12,12a at an extreme end of a distal end portion of the tube (see entire document, especially figs. 2 and 4 of Crawford).

The applicants further contend that the needle 11 does not include the recited fluid communication pathway that is formed between the insertion tube and an elongated member. Applicants' arguments here are largely based on the language that has been deemed incongruous with other limitations of the claims, as discussed above in the rejections under 35 U.S.C. 112, 1st and 2nd paragraphs. Since the amended claims do not make sense, the claims are being interpreted in light of the disclosure, as

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originally filed. See the rejection under 35 U.S.C. 112, 2nd paragraph for the interpretation of the claims in light of the unclear language.

Therefore, the rejection of claims 1, 3-8, 10, 14, and 20-27 as being anticipated by Crawford stand.

Allowable Subject Matter

Claims 9, 11, 15, and 16 are allowed. The allowability of claims 9 and 15 was first addressed in an Office action filed 4/20/05. The allowability of claims 11 and 16 was first addressed in Office action filed 6/30/06. The reasons for allowance of claims 9, 11, 15, and 16 were repeated in the Office action filed 5/22/07.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Examiner, Art Unit 3735